EXHIBIT 12

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIOID LITIGATION	MDL No. 2804 Case No. 17-md-2804
CITY OF CLEVELAND OHIO and THE STATE OF OHIO EX REL. ET AL Plaintiffs, v. PURDUE PHARMA L.P., ET AL Defendants.	Judge Dan Aaron Polster

AMENDED EXPERT REPORT OF SANDRA K.B. KINSEY, R.Ph, MBA.

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i) Giant Eagle is a small grocery chain with a relatively small pharmacy business. Recognizing the complex differences to the core organization, Giant Eagle built a pharmacy infrastructure that is separate from its main grocery business in order to focus on patient care, prescription delivery and cost, supply chain, regulatory compliance, training and other health related business services. This independence enables the pharmacy to operate with efficiency and accuracy because of the redundant layers of oversight by specially trained and educated employees.

j) Giant Eagle's inventory management system consists of integrated controls within the corporate office, distribution center and pharmacy to prevent theft and diversion of all prescription products. Because of the heightened sensitivity concerning controlled substances, and opioids in particular, additional parameters are engaged that exceed regulatory minimums.

k) Giant Eagle is, and always has been, compliant with the Controlled Substances Act as evident by their continued licensing by the Ohio State Board of Pharmacy, the Pennsylvania, West Virginia, Maryland and Indiana State Boards of Pharmacy and the Drug Enforcement Agency for every store in the respective states as well as for the HBC Services Company (HBC) and Giant Eagle Rx (GERx) distribution centers. Because of their robust and cohesive processes to prevent theft and diversion before it occurs, it is not surprising that only a limited number of

orders were identified as part of their comprehensive design of SOM systems and safety controls.

II. OVERVIEW OF THE OPIOID MARKET

A. A Brief Review of Opioids and the Controlled Substances Act

18. Opioids have been regarded for millennia as among the most effective drugs for the treatment of pain.[5] Opioids are a group of narcotic pain-relieving drugs which act by interacting with opioid receptors in the brain, spinal cord and other areas of the body to interrupt the pain response pathway. Opioids can be made from the poppy plant, such as morphine, or synthesized in a laboratory, such as fentanyl. Opioids are used as an anesthesia, cough suppressant, diarrhea suppressant and for the management of pain arising from various diseases and injuries.[6] According to the National Institutes of Health, a division of the U.S. Department of Health and Human Services (HHS), opioids are "generally safe when used for a short time and as prescribed by a doctor."[7]

19. According to research from 2016, the opioid market is witnessing growth due to increasing prevalence of orthopedic diseases and other chronic pain afflictions, rising focus on abuse-deterrent formulations, growth of palliative care initiatives and facilities, and an inclination toward extended release formulations from the immediate release alternatives.[8]

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[5] Rosenblum, A., Marsch, L. A., Joseph, H., & Portenoy, R. K. (2008). Opioids and the treatment of chronic pain: Controversies, current status, and future directions. *Experimental and Clinical Psychopharmacology, 16*(5), 405-416, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/ (last accessed May 3, 2019).

[6] Opioids Market by Product (Morphine, Codeine, Fentanyl, Meperidine), Receptor Binding (Strong Agonist, Mild to Moderate Agonist), Application (Pain Management, Cough Suppression, Diarrhea Suppression), Region (North America, Europe, Asia, RoW) – Global Forecasts to 2023, *available at* https://www marketsandmarkets.com (last accessed May 3, 2019).

[7] How Opioid Drugs Activate Receptors (2018), *available at* https://www nih.gov/news-events/nih-research-matters/how-opioid-drugs-activate-receptors (last accessed May 3, 2019).

[8] Opioids Market by Product (Morphine, Codeine, Fentanyl, Meperidine), Receptor Binding (Strong Agonist, Mild to Moderate Agonist), Application (Pain Management, Cough Suppression, Diarrhea Suppression), Region (North America, Europe, Asia, RoW) – Global Forecasts to 2023, *available at* https://www marketsandmarkets.com (last accessed May 3, 2019).

49. As self-proclaimed "Pioneers of the Modern Supermarket", Giant Eagle continually innovates with store design, technology advancements and new service offerings for customer convenience and loyalty. In the 1980s, Giant Eagle built upon the store-within-a-store concept by adding pharmacy, floral, automotive, housewares, books, greeting cards, photo development and video rentals.[29] Giant Eagle also built the world's first LEED-certified supermarket, receiving numerous local, state, and federal awards for its commitment to environmental sustainability and waste reduction.[30]

50. Giant Eagle operates more than 400 retail locations of various sizes, including 120,000 square-foot supermarkets to small neighborhood markets, as well as fuel and convenience locations[31]. Within the enterprise, Giant Eagle operates only 227 pharmacies.[32]

51. Even with its relatively small footprint, Giant Eagle is recognized as one of the 20 most influential retailers in the United States.[33] Among other highlights, Giant Eagle is praised for their pharmacy offerings and their ability to successfully compete against Rite Aid, once the third-largest retail drugstore chain in the country and headquartered in Pennsylvania.[34] Industry leaders regard Giant Eagle as the "perfect combination of pharmacy, food and fuel as something to really give value to consumers in their greater Pennsylvania, Ohio and contiguous markets. They're one of the leaders in pharmacy."[35]

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[29] https://www.gianteagle.com/about-us/our-history (last accessed May 3, 2019).
[30] https://www.gianteagle.com/about-us/our-history (last accessed May 3, 2019).
[31] https://www.gianteagle.com/about-us/press-room (last accessed May 3, 2019).
[32] "Weekly Rx Volume by store (A1366710).xlsx".
[33] DSN's 2019 Retail Pacesetters Report (May 7, 2019), *available at* https://www.drugstorenews.com/retail-news/dsns-2019-retail-pacesetters-report/ (last accessed May 8, 2019).
[34] https://www.riteaid.com/about-us/our-story (last accessed May 8, 2019).
[35] Hamstra, M. 2019: Retail Pacesetters: Giant Eagle Offers Value in Food, Fuel and Pharmacy (May 7, 2019), *available at* https://www.drugstorenews.com/retail-news/2019-retail-pacesetters-giant-eagle-offers-value-in-food-fuel-and-pharmacy/ (last accessed May 8, 2019).

B. Giant Eagle Pharmacy

52. Giant Eagle owns and operates 227 pharmacies in five states: Pennsylvania, Ohio, West Virginia, Maryland and Indiana. Of the 227 pharmacies, 27 pharmacies are in Cuyahoga County and 13 pharmacies in Summit County. Giant Eagle's pharmacy business is comprehensive and includes a well-developed specialty pharmacy operation for patients with complex therapy needs, along with an extensive prescription delivery program and a dedicated pharmacy mobile application to drive awareness, therapy compliance and patient education.

53. Giant Eagle Pharmacy experienced rapid growth beginning in 2008 and peaking in 2012 after new store growth slowed. Consistent with the decline in new construction, the pharmacy business began experiencing a decrease in annual prescription volume, compounded by 90-day fills, mandatory mail order and insurance exclusivity that affected many other pharmacy organizations.

C. Customer Demographics in Cuyahoga County and Summit County

54. In 2017, Cuyahoga County, OH had a population of 1.25M people with a median age of 40 and a median household income of approximately $47,000, which is lower than the national average. The population is 59% Caucasian, 29% Black or African American, and 6% Hispanic or Latino.[36]

55. The largest industry in Cuyahoga County is health care and social assistance. Registered nurses, health technologists and health technicians are among the most common jobs held by residents. In addition, Cuyahoga County has an unusually high number of physicians and surgeons compared to other counties.[37] Much of this is due to the abundance of health care offerings, including the renowned Cleveland Clinic Health System and University Hospitals

[36] https://datausa.io/profile/geo/cuyahoga-county-oh/ (last accessed May 3, 2019).
[37] https://datausa.io/profile/geo/cuyahoga-county-oh/#economy (last accessed May 3, 2019).

72. HBC/GERx distributed a very small fraction of all prescription opioids dispensed in Cuyahoga and Summit counties during the relevant time period. Between 1996 and 2018, the amount of prescription opioids distributed by HBC and GERx in the two counties was [redacted]% on an MME basis and [redacted]% on a dosage unit basis. For the period 2006 to 2014, HBC's share of opioids distributed in the two counties was [redacted]% on an MME basis. See Exhibit D.

73. HBC/GERx distributed only a small proportion of prescription opioids dispensed in Cuyahoga and Summit counties on a per capita basis during the relevant time period. See Exhibit E and Exhibit F. These data also show no shipments of prescription opioids by HBC or GERx between October 2014 and March 2016.

74. The volume of HCPs distributed by HBC/GERx generally tracked below quotas set by the DEA. See Exhibit G. The data shows that distribution of hydrocodone combination products from HBC was below the expected amount on an MME basis between 2012 and 2017 when indexed to the DEA quota for hydrocodone products starting in 2010. The data also shows no shipments of any HCPs from HBC or GERx during 2015.

75. Based on my analysis of the data presented above, I conclude that HBC/GERx account for a very small share of the total market for the distribution of prescription opioids in Summit and Cuyahoga counties, and that the share of HCPs distributed by HBC and GERx declined over time relative to production quotas for hydrocodone established by the DEA.

2. Dispensing of Controlled Substances by Giant Eagle Pharmacies

76. Giant Eagle pharmacies dispense a wide range of prescription drugs, typical of legitimate retail pharmacies, including both controlled substances and other non-controlled prescription drugs. The ratio of controlled substance prescriptions to total prescriptions dispensed, for all Giant Eagle pharmacies in Summit and Cuyahoga counties during the relevant time period was less than 10%. See Exhibit H. Notably, this data contains all controlled

substance transactions, concluding that the ratio of only HCP to total prescriptions is substantially less than 10%. And, although there is no precise threshold for the proportion of controlled substance prescriptions relative to other (non-controlled) prescription drugs above which it would be standard industry practice to investigate distributor transactions, a ratio of approximately 20% controlled to 80% non-controlled prescriptions is commonly accepted.[47]

77. The ratio of controlled substance prescriptions to total prescriptions dispensed by Giant Eagle pharmacies declined over the relevant time period, from a high of approximately 12% in 2009 to less than 8% in 2018. See Exhibit I.

78. In 2014, across regions where Giant Eagle has a presence (e.g., Western Pennsylvania and parts of Ohio, West Virginia, Maryland, and Indiana), the stores' market share for prescriptions for at-issue hydrocodone and oxycodone products was 18.60%, compared with a market share of 24.41% for non-controlled prescription drugs dispensed by Giant Eagle pharmacies. See Exhibit J. In 2015, the Giant Eagle share of the market in the same regions for these at-issue controlled substances declined to 16.99%, compared with 23.35% for non-controlled prescription drugs.

79. Based on the data presented above, I conclude that Giant Eagle pharmacies in Summit and Cuyahoga counties dispense a wide range of prescription drugs that meet the healthcare needs of Summit and Cuyahoga counties, dispensing a smaller share of prescription opioids compared to other retail pharmacies and filling a modest number of prescriptions for controlled substances that is well below the level expected for legitimate retail pharmacies. During the relevant time period, the share of prescriptions for controlled substances dispensed by

[47] Deposition of Kyle J. Wright, February 28, 2019, at 260:1-22.

Giant Eagle pharmacies declined steadily, indicating that the pharmacies were exercising effective controls to prevent diversion of prescription opioids.

80. Considering the relative size of HBC/GERx discussed in section III.F.1 above and the smaller share of prescription opioids dispensed by Giant Eagle pharmacies discussed in ¶ 79, HBC and GERx were de minimis distributors of at-issue opioids in Cuyahoga and Summit Counties.

IV. RETAIL DRUG DISTRIBUTION AND INVENTORY MANAGEMENT

A. Prescription Filling Process

81. To understand how prescription drugs are prescribed and dispensed, it is important to understand how the process is influenced by several decision makers, including prescribers, pharmacists, insurers, and patients, as well as the regulatory and institutional features of the marketplace that influence which drugs are prescribed and dispensed.

a) The Role of the Prescriber

82. The first step in the process occurs when a prescriber writes a prescription for a patient. In general, a patient seeks medical treatment, the prescriber examines the patient, reviews their medical history, performs any necessary tests, and then uses their extensive knowledge and experience to determine the diagnosis. The prescriber will then develop a specific treatment plan, which often requires one or more prescription drugs.

83. When a prescriber writes a prescription for a patient, the prescription specifies a certain drug molecule. The specific drug may be designated using the marketed brand name (such as Norco™) or by using the "generic" or active ingredient name (such as Hydrocodone/APAP). The prescription also will specify a certain dosage form (e.g., tablet, capsule, elixir), the strength (e.g., 5 mg vs. 10 mg), and specific directions for use (e.g., take once or two tablets by mouth every four to six hours as needed for pain).

93. All pharmacies use a prescription management system ("PMS") to assist them in the prescription-filling process and to prompt specific interventions for operational and legal compliance. Regardless of the specific software application used to run a PMS, most of the functionality is consistent. This software can be, and often is, customized by individual users.

94. During the prescription filling process, the pharmacist will assess the prescriber information and determine if and how a prescription is dispensed per the prescription instructions. Pharmacies play an integral role in determining the legitimacy of prescriptions. Because of safety and compliance, theft and diversion concerns surrounding controlled substances, these prescriptions are scrutinized with a more focused lens. According to the DEA, "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[53] The regulation clearly states that the prescribing practitioner has full responsibility for proper prescribing and dispensing of controlled substances. The regulation also indicates a corresponding responsibility of the pharmacist who fills the prescription. Controlled substance prescriptions have different regulations than standard legend drugs and the pharmacist will ensure the prescribed information is accurate before continuing the process.

95. In addition to assessing the accuracy of the prescribed information, the pharmacist will reference any available and applicable state monitoring system, such as the Ohio Automated Rx Reporting System ("OARRS"). These systems are designed to monitor controlled substance prescriptions and can give a prescriber and pharmacist critical information regarding a patient's medication history of controlled substance usage.

[53] 21 C.F.R. § 1306.04.

96. It is not the role or obligation of the pharmacist to challenge a doctor's diagnosis or treatment plan, however, if there are questions regarding the prescription, a pharmacist will communicate with the prescriber regarding a prescription to discuss the drug, strength, dose or frequency of utilization for a specific patient and discuss the appropriate course of action as part of their "corresponding obligation". A pharmacist may not alter a prescriber's treatment regimen without prescriber's consent. However, a pharmacist may, at any time, exercise their professional judgement and refuse to fill a prescription that appears fraudulent, outside the scope of practice or not in accordance with standard treatment guidelines.

97. Once the prescribed information is evaluated, pharmacies will dispense the most cost-effective drug based on the prescription and state-specific drug-selection and substitution laws. Most pharmacies will dispense an FDA-approved, A-rated generic drug, rather than the brand name drug prescribed by the physician, if the following criteria are met: (a) an FDA-approved, A-rated generic drug is available for substitution; (b) the pharmacy has the drug in stock; (c) the patient's insurance company approves reimbursement for the substituted drug; and (d) the prescriber has not taken any step to prevent substitution, such as prescribing the brand name drug *and* specifying that it must be dispensed as written (DAW).

c) Insurance Coverage and Adjudication

98. Adding another level of control, checks and balances, health insurance organizations orchestrate an elaborate review and approval process prior to a prescription being dispensed. Over 90% of all prescriptions are filed and adjudicated with third-party insurance companies.[54] Health insurers, including private companies as well as Medicare, Medicaid, and

[54] "Why Retail Pharmacies Still Overcharge Uninsured Patients," Drug Channels (Apr. 19, 2018), *available at* https://www.drugchannels.net/2018/04/why-retail-pharmacies-still-overcharge.html (last accessed May 3, 2019).

watch trends in the industry and within their area of responsibility and will adjust forecasts as the needs of the business change. Any unexpected changes are researched thoroughly to either take advantage of the upsides or mitigate the opportunities of any risk that may be presented. Unexpected changes in inventory levels or orders for controlled substances are researched thoroughly as part of theft and diversion controls.

121. At Giant Eagle, corporate buyers utilize a computerized inventory management system to control and closely monitor all orders at the warehouse. This includes incoming and outgoing orders between the stores and the distribution center and the incoming orders from manufacturers to the distribution center.

V. GIANT EAGLE'S COMPLIANCE WITH CONTROLLED SUBSTANCES ACT

A. CSA Obligations

122. The Controlled Substances Act of 1970 is a statute that establishes US drug policy and creates a system for the legitimate manufacturing, distribution, and prescribing/dispensing of controlled substances. Each registrant within this "closed system of distribution" has defined privileges and responsibilities in which they must operate. Once the prescription is dispensed and leaves the control of the pharmacy, the patient assumes responsibility for using the drug as prescribed, keeping it safe and disposing of unused portions appropriately.

123. With a concentration on delivering exceptional patient care, Giant Eagle fulfills its obligations to and is in compliance with the provisions outlined in the Controlled Substances Act. Giant Eagle maintains an integrated infrastructure of interdependencies beginning with the pharmacy, through the distribution center and extending into oversight from leadership in the corporate office consistent with industry standards. Giant Eagle is highly focused on preventing theft and diversion by, in many cases, exceeding expectations related to federal and state guidelines. The DEA and State Boards of Pharmacy perform comprehensive inspections and

audits of Giant Eagle pharmacies and HBC/GERx to test and approve sufficient controls are in place and effective. Giant Eagle and the DEA maintain a cooperative and engaging relationship and the DEA has never sanctioned Giant Eagle for failure to comply with any regulation or found them deficient in any controls.[67].

124. Summarizing the CSA, 21 CFR §1301.71, it states that, "All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." The statute continues with, "…the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion" and that, "Substantial compliance with the standards set forth in Secs. 1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant."[68]

B. Physical Security and Controls

125. 21 CFR §1301.72 details the physical security controls required for CII substances and CIII-CV. In accordance with the regulations, both HBC and GERx meet or exceed each of these requirements. For example:

- All controlled substances are housed in a steel cage or vault and no cross-docking allowed
- Security cameras, video surveillance and guards monitor the facilities
- For outbound product, inventory is counted before the business day starts, when it ends and prior to scheduled breaks
- For inbound product, inventory is counted at point of receipt and reserves slots verified

[67] Deposition of George Chunderlik, dated January 16, 2019, p. 266.
[68] 21 CFR §1301.71.

and managed according to state, federal, and corporate regulations and policies. It is not surprising, however, that the number of documented and reported situations is limited. As explained, Giant Eagle has a complex, integrated system of controls that is aimed at preventing THEFT AND DIVERSION BEFORE IT CAN BEGIN.

VI. DR. MCCANN'S FLAGGING METHODOLOGIES

A. Context for the Use of Threshold-Based Methods in Identifying Suspicious Orders

144. Giant Eagle's HBC and GERx distribute prescription drugs solely to Giant Eagle retail pharmacies that are owned, operated and managed by the same parent company, Giant Eagle, Inc. In my experience, shipments of controlled substances within divisions of the same company are subject to an inherently lower risk of diversion than transactions with external customers. Although monitoring and reporting of shipments of controlled substances between distribution centers and retail pharmacies within Giant Eagle are required by the Controlled Substances Act, the use of threshold-based methods (i.e., algorithms that apply historical or pre-set thresholds of order frequency, dosage, or other characteristics) to identify potentially suspicious orders from customers are not required by the Controlled Substances Act. Furthermore, such threshold-based methods are neither an effective nor a rational means to detect diversion of controlled substances for shipments between divisions of the same company. The DEA warns against registrants utilizing and relying on rigid formulas to identify suspicious orders. Only orders labeled and confirmed as "suspicious" by the registrant should be submitted to the DEA. Simply communicating "excessive purchases" do not comply with the requirement.[78]

[78] See DEA Letter from J. Rannazzisi to All Registrants, dated June 12, 2012. ABDCMDL00269683.

B. Dr. McCann's Dataset Is Flawed

145. The dataset Dr. McCann uses in his "Transaction Analysis"[79] for HBC contains errors. Specifically, his dataset contains 4,206 duplicate transactions. This is not an error in the HBC data production, but rather in Dr. McCann's use of the company's data. In addition to the fact that plaintiffs' expert's analysis should not contain data errors of his own creation, the duplicate data biases the results of his "transaction analyses." For the following stores, which are in Cuyahoga county and included in GE's Cuyahoga production and its Cleveland production, Dr. McCann's dataset includes duplicates of every transaction between March 2016 and May 2018: Parma, Cleveland, Brookpark, Lakewood, Middleburg Heights, Brooklyn, Garfield Heights, South Euclid, and Beachwood.

C. Dr. McCann's "Transaction Analysis" Is Flawed

146. Dr. McCann implemented "various approaches to identify transactions meeting specified criteria using the non-public ARCOS Data from 2006 to 2014, supplemented with Defendant transaction data."[80] He presents five different "approaches," which result in a large number of transactions between HBC and Giant Eagle pharmacies being "flagged."[81] Dr. McCann does not explain the basis for the approaches or what expertise he applied in developing these approaches. Furthermore, Dr. McCann does not express an opinion regarding the results or apply any expertise to the interpretation of the results. Rather, he states: "I have been asked by Counsel to assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction."[82]

[79] McCann Report, §IX, pp. 56-81.
[80] McCann Report, p. 56.
[81] McCann Report, Tables 24-33.
[82] McCann Report, p. 56.

147. Dr. McCann's transaction analyses suffer from several common flaws. As I discussed above, one fatal flaw is that Dr. McCann's dataset contains glaring errors — thousands of duplicate transactions — that lead to spurious results. Yet another fatal flaw that spans his transactions analyses is that Dr. McCann is using unproven, nonstandard, unprincipled methodologies that are void of research and application of widely accepted professional principles. An additional fatal flaw, which illustrates that Dr. McCann's approaches are not based on professional pharmaceutical practices or theory, is the fact that his unit of measurement for transactions is at the level of the active pharmaceutical ingredient (API). In my experience, it is not appropriate to evaluate pharmaceutical distribution practices exclusively at level of APIs. The wide range of potential formulations and dosages for a given API can result in products with very different characteristics. For example, under Dr. McCann's API focused approaches, a dosage unit of 5 mg oxycodone and 325 mg of acetaminophen is equivalent to a dosage unit of 80 mg of oxycodone despite their different ingredients, degrees of potency and varying transactional volume. Finally, in all five of Dr. McCann's approaches, Dr. McCann flags all transactions subsequent to the first flagged transaction. This means that he automatically impugns all subsequent transactions without an analysis of the fundamental properties of the transactions, thereby abandoning whatever modicum of professional principle might have supported his approach.

148. As a consequence of this failure to base his evaluation of transactions on professional pharmaceutical practices, there is no legitimate basis for Dr. McCann's thresholds, which he relies on to determine whether transactions should be "flagged," and the product of his "transactions analysis" is spurious results that can only be interpreted by counsel for the plaintiffs. Dr. McCann does not rely on any healthcare or pharmacy expertise, in the

interpretation of the results. In the sections below, I describe additional flaws that are specific to one or more of the individual approaches he has proposed.

D. Maximum Monthly, Trailing Six-month Threshold

149. Dr. McCann describes his first transaction analysis approach using the following language: "I identify transactions that cause the number of dosage units [for a particular drug (e.g., hydrocodone)] shipped by a Distributor [e.g., HBC] to a Pharmacy [e.g., Giant Eagle pharmacy in Cuyahoga or Summit counties] in a calendar month to exceed the highest number of dosage units shipped by the Distributor to the Pharmacy in any one of the six preceding calendar months."[83] Dr. McCann does not explain why this is a reasonable approach and whether the results of this approach are reasonable. I see no basis of support for this approach in the principles of patient care, distribution of pharmaceuticals, distribution of controlled substances or pharmacy supply and management. In addition to all the systemic flaws in Dr. McCann's transaction analyses, a flaw specific to this six-month approach is that it cannot control for increased shipments of opioids because of growth in overall store business; this approach merely identifies stores that are growing in their order volume.

150. For a given distributor/pharmacy/drug combination in a given month, Dr. McCann calculates a pharmacy-specific threshold which is the maximum monthly total dosage units during the previous 6 months of transaction data. This pharmacy-specific threshold changes every month, reflecting the trailing 6-month period. If the store-specific maximum monthly dosage units are less than 1,000, Dr. McCann uses 1,000 dosage units as the threshold; in other words, in his 6-month trailing maximum approach, the store-specific monthly threshold for flagged transactions for any drug is always greater than or equal to 1,000 dosage units. In the

[83] McCann Report, p. 56.

case of HBC, the company started supplying Giant Eagle pharmacies with Schedule III opioids (HCP and codeine combination product) in November 2009; 38 of the 39 Giant Eagle pharmacies located in Cuyahoga and Summit counties were open in November 2009 and reported receiving a shipment of HCP on November 12 or 13, 2009.[84] The first month of HCP transactions Dr. McCann scrutinizes using the trailing 6 month maximum approach is May 2010, the seventh month after shipments of HCP commence. Under this approach, Dr. McCann flags HCP transactions between HBC and all 38 stores in 2010. For a given distributor/pharmacy/drug combination, all transactions subsequent to the first flagged transaction are also flagged. In the case of HBC, Dr. McCann does not explain why it is reasonable to flag all transactions involving GERx, which began shipping Schedule II opioids to Giant Eagle pharmacies in March 2016, 18 months after HBC ceased shipping HCP and codeine combination products to Giant Eagle pharmacies.

151. To illustrate the fact that Dr. McCann's "maximum monthly, trailing six-month threshold" approach merely identifies stores that were experiencing overall sales growth, I have prepared Exhibit M, which presents four examples of his application to the Giant Eagle data. Using his "maximum monthly, trailing six-month threshold" approach, Dr. McCann concludes that the earliest flagged transaction between HBC and Giant Eagle store #0218, located in Garfield Heights (Cuyahoga County), involving any product with the API hydrocodone was on August 29, 2010 (the first example presented in Exhibit M.) This is based on a determination that the monthly total dosage units for all transactions between HBC and store #0218 was 10,030, which is greater than the trailing six-month maximum of 9,330 dosage units observed in June 2010. He further determines that within the month of August 2010, the transaction on

[84] The 39th store, #4088 in Cuyahoga county, reported the first shipment of HCP on April 23, 2012.

August 29, 2010 caused the cumulative monthly total dosage units shipped by HBC to the store to exceed the threshold of 9,330. My Exhibit M also reports total growth in prescriptions filled by the pharmacy between Dr. McCann's threshold month (June 2010 for store #0218) and the month of the first transaction (August 2010 for store #0218), and the monthly share of controlled prescriptions in the threshold month and the month of the first transaction. For store #0218, total monthly prescriptions grew 34% between June and August 2010. Over the same time interval, controlled substance prescriptions, as a share of all prescriptions filled, remained stable at 11%-12%. The growth in dosage units of HCP products shipped that Dr. McCann claims should have been flagged for investigation can be simply explained as a consequence of overall growth in business at store #0218 over the three-month period. The example of store #0218 illustrates my conclusion that Dr. McCann's "maximum monthly, trailing six-month threshold" approach is incapable of distinguishing between periods when total sales are increasing and periods when sales of a particular product are increasing in a manner that could warrant further investigation.

E. Twice Trailing Twelve-Month Average Pharmacy Dosage Units

152. Dr. McCann describes his "twice trailing twelve-month average pharmacy dosage units" transaction analysis approach using the following language: "I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed twice the trailing twelve-month average dosage units to retail and chain pharmacies served by the Distributor." It is important to note that this approach does not create a store specific threshold. Consequently, in addition to all the systemic flaws in Dr. McCann's transaction analyses, which I discussed at the beginning of this section, there are three additional flaws specific to the trailing twelve-month average approach. The first flaw is that for any given month, the threshold is based on monthly average sales for all stores to which the distributor

shipped.[85] For this reason, this approach is inherently biased against stores with a larger volume of prescriptions dispensed to a larger patient base. The second flaw specific to the trailing twelve-month average approach is that, as Dr. McCann has implemented it, the Giant Eagle pharmacies that were not flagged during the period in which HBC was shipping Schedule III opioids (November 2009 - September 2014) are flagged using only one to seven months of transaction data in 2016. A third flaw is that, as implemented, this approach is logically inconsistent with Dr. McCann's assumption in the "maximum monthly, trailing six-month threshold" approach that monthly total transaction volume of 1,000 dosage units or less should not have been flagged for investigation. I discuss these approach-specific flaws in more detail below.

153. Under his twice trailing twelve-month average method, Dr. McCann flags HBC HCP transactions at six of Giant Eagle's largest pharmacies between November 2010 (the thirteenth month after HBC began shipping HCP to Giant Eagle pharmacies) and January 2011, and a seventh store in April 2013. Dr. McCann flags transactions involving all of the remaining 32 Giant Eagle pharmacies in Cuyahoga and Summit counties in 2016, long after HBC had ceased shipments of opioids to GE pharmacies. Using this approach for HCP transactions, he flags one store in April 2016 and the remaining 31 stores in September 2016 (17 pharmacies) and October 2016 (14 pharmacies). Notably, in April 2016, GERx had been shipping HCP to Giant Eagle pharmacies for only one month; GERx began shipping HCP in mid-March 2016. Thus, the threshold he uses to evaluate April 2016 shipments is based on only one month (March 2016) of prior transactions, not twelve months as stated in his report. The threshold he uses to evaluate and flag September 2016 shipments is based on only six months (March-September 2016) of

[85] My review Dr. McCann's of extensive reliance materials is ongoing and I may supplement my opinions as a result.

prior transactions, not twelve months as stated in his report. The threshold he uses to evaluate and flag October 2016 shipments is based on only seven months (March-October 2016) of prior transactions, not twelve months as stated in his report.

154. The "twice trailing twelve-month average pharmacy dosage units" and method is logically inconsistent with the "Maximum Monthly, Trailing Six-month Threshold" method because the 6-month metric assumes that for all distributor/pharmacy/drug combinations the threshold cannot be less than 1,000 dosage units. In contrast, the "Twice Trailing Twelve-Month Average Pharmacy Dosage Units" approach does result in initially flagged transactions based on a threshold of less than 1,000 dosage units per month. For instance, the threshold for monthly HCP transactions in April 2016, under the twice trailing twelve-month average approach, was [redacted] dosage units. Dr. McCann calculates this threshold based solely on HCP transactions in March 2016. GERx shipped two orders of HCPs totaling [redacted] dosage units on April 12, 2016 to Giant Eagle Pharmacy #1263. These were the only transactions between GERx and pharmacy #1263 in April 2016. Based on the threshold of [redacted] dosage units, Dr. McCann flags both shipments (and every HCP transaction for pharmacy #1263 thereafter). There are additional examples of Dr. McCann flagging other Giant Eagle pharmacies based on thresholds of less than 1,000 dosage units per month.

155. Based on my review of Dr. McCann's "Twice Trailing Twelve-Month Average Pharmacy Dosage Units" approach, I conclude that Dr. McCann did not accurately explain his methodology and that the approach he used is internally, logically inconsistent. Moreover, Dr. McCann does not explain why this is a reasonable approach and whether the results of this approach are reasonable. I see no basis of support for this approach in the principles of patient

care, distribution of pharmaceuticals, distribution of controlled substances or pharmacy supply and management.

F. Three Times Trailing Twelve-Month Average Pharmacy Dosage Units

156. Dr. McCann's "three times trailing twelve-month average pharmacy dosage units" approach is similar to the "Twice Trailing Twelve-Month Average Pharmacy Dosage Units" I discussed above, with the exception that he multiplies the 12-month average by three rather than by two. The three times 12-month approach therefore suffers from the same fatal flaws, both systemic and specific to the trailing twelve-month average approach, that afflict the twice 12-month approach. It is biased against larger store volumes when calculated using 12-months of transactions.[86] The approach also results in 31 Giant Eagle pharmacies being flagged for HCP transactions in September and October 2016, before 12 months of GERx shipments have occurred.

157. Based on my review of Dr. McCann's "three times trailing twelve-month average pharmacy dosage units" approach, I conclude that Dr. McCann did not accurately explain his methodology and that the approach he used is internally, logically inconsistent. Moreover, Dr. McCann does not explain why this is a reasonable approach and whether the results of this approach are reasonable. I see no basis of support for this approach in the principles of patient care, distribution of pharmaceuticals, distribution of controlled substances or pharmacy supply and management.

G. Maximum 8,000 Dosage Units Monthly

158. Dr. McCann describes his "Maximum 8,000 Dosage Units Monthly" approach using the following language: "I identify transactions that cause the number of dosage units

[86] My review Dr. McCann's of extensive reliance materials is ongoing and I may supplement my opinions as a result.

shipped by a Distributor to a Pharmacy in a calendar month to exceed 8,000 dosage units." In addition to the systemic flaws that afflict all of Dr. McCann's transaction analyses, there are several fatal flaws specific to the "Maximum 8,000 Dosage Units Monthly" approach. First, although Dr. McCann does not discuss the basis for the 8,000 dosage unit threshold in his report, I understand that this is a metric that McKesson may have developed and/or used at some point in time.[87] Dr. McCann provides no explanation for why it is reasonable to apply a metric developed by a third party to HBC transactions. Second, a hard limit such as 8,000 monthly dosage units is biased against larger stores. Third, according to Dr. McCann, McKesson used this metric for oxycodone, with no indication as to whether it applied to all formulations or just some. Additionally, it is not clear whether McKesson used this metric to evaluate shipments of other opioids, such as HCP or codeine. Dr. McCann provides no justification for why an 8,000-dosage-unit threshold is relevant for all formulations of oxycodone and no basis for his use of this metric as a threshold for shipments of drugs other than oxycodone.

H. Maximum Daily Dosage Units

159. Dr. McCann describes his "maximum daily dosage units" approach using the following language: "I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a day to exceed a number of dosage units that varies by drug type and within some drug types by formulation." Although, as of today, I have not been able to evaluate the basis for the thresholds Dr. McCann uses in his "Maximum Daily Dosage Units" approach,[88] I note that the results of this approach are absurd. For example, for HCPs, the very first transaction is flagged for all 39 Giant Eagle pharmacies in the two counties (i.e., the first

[87] My review Dr. McCann's of extensive reliance materials is ongoing and I may supplement my opinions as a result.

[88] I have been unable to locate the source documents that Dr. McCann claims to have relied on as the basis for his maximum daily dosage unit thresholds.

day HBC ships HCPs). I will supplement my opinions regarding this approach after I have been able to review and evaluate the source documents that Dr. McCann claims to have relied on for this approach.

I. Chain Distributor Transactions Analyses

160. In section IX.F of his report, Dr. McCann describes an additional set of transaction analyses he conducted, which he describes as "additional identification" in the section title and a "chain distributor" transaction analyses in the text of his report and his reliance materials. Dr. McCann describes his "chain distributor" transaction analyses using the following language: "I have been asked by Counsel to assume that Chain Distributors may have had knowledge of – or information available to inform them of – opioid shipments from all Distributors to the Chain Distributor's affiliated pharmacies. I have re-run the five identification routines described above assuming that the Chain Distributors could have flagged transactions based on this expanded information set…"

161. In addition to the systemic and approach-specific flaws I describe above, Dr. McCann's "chain distributor" transaction analyses suffer from two additional glaring errors with respect to HBC. First, Dr. McCann's "chain distributor" transaction analyses assume that HBC can be liable for the actions of other distributors in the market. Second, Dr. McCann concludes that HBC is responsible for monitoring distributor transactions before it was in the business of distributing Schedule III-V controlled drugs to Giant Eagle pharmacies (i.e., before November 2009).

162. These analyses are conducted over the period 2006-2014, based on all distributor transactions with Giant Eagle pharmacies. For all opioids at issue in this case, Dr. McCann flags a large number of transactions before HBC started shipping opioids to Giant Eagle pharmacies. For example, Dr. McCann performed the analysis on the pharmacy/drug level, and he did start

flagging transactions before 2009. For example, for Giant Eagle pharmacy #0209 for the Codeine (9050) products, the first failed flagged transaction using all distributor transaction data and the "Twice Trailing Twelve-Month Average Pharmacy Dosage Units" approach is February 26, 2007 (a shipment from McKesson). This store did not receive shipments of codeine combination products from HBC before October 12, 2009. Another example is HCP shipments to Giant Eagle pharmacy #1216. The first failed flagged transaction using all distributor transaction data and the "Maximum Monthly, Trailing Six-month Threshold" approach is August 28, 2006 (a shipment from McKesson). The first transaction Dr. McCann flags under the 6-month threshold is from McKesson on August 28, 2006. This store did not receive shipments of hydrocodone combination products from HBC before October 12, 2009. For HCPs, Dr. McCann flagged 41,568 transactions between January 3, 2006 and November 11, 2009. For all of these transactions involved, Giant Eagle was not the distributor. Moreover, during this period HBC was not a distributor; the company did not ship a single dosage unit of any opioid to any pharmacies. See Exhibit N.

163. Dr. McCann does not explain why the "Chain Distributor" approach analyses is reasonable and whether the results of this approach are reasonable. I see no basis of support for this approach in the principles of patient care, distribution of pharmaceuticals, distribution of controlled substances or pharmacy supply and management.

VII. ORDERS IDENTIFIED BY PLAINTIFFS AS SUSPICIOUS WERE BASED ON VALID PRESCRIPTIONS DISPENSED UNDER THE PROPER AUTHORITY

164. Plaintiffs identified 30 HBC orders that they claim are suspicious.[89] I understand from counsel for HBC that Giant Eagle determined that none of these orders were suspicious based on a thorough investigation of the associated prescriptions. My review of these orders, including the size and frequency of other orders during the relevant periods, did not identify a suspicious pattern.

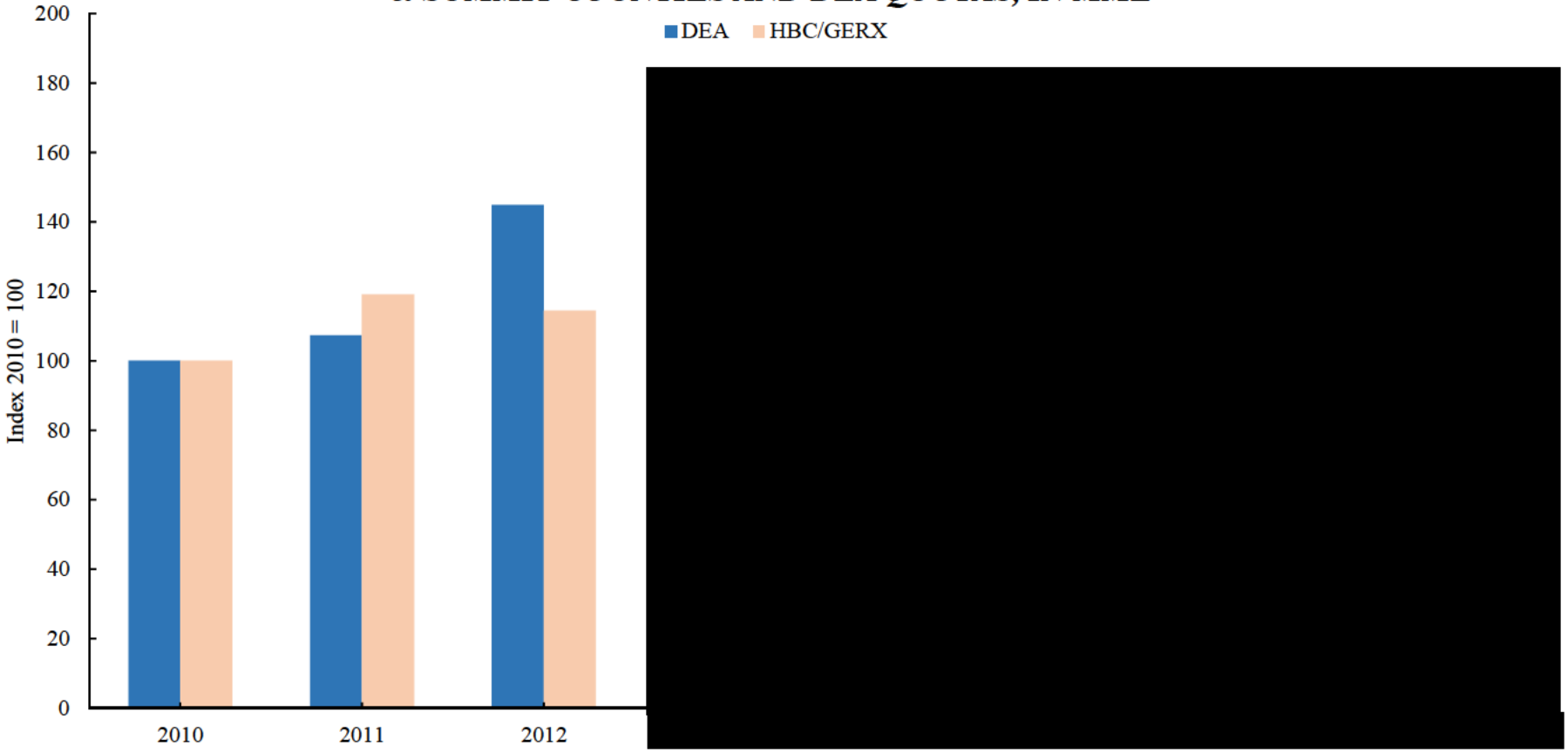
165. The Giant Eagle pharmacy located in Barberton, Ohio (#4031) is the buyer for all 10 orders identified by plaintiffs in the supplemental interrogatory dated January 11, 2019 and in 2 of the 20 orders identified by plaintiffs in the amended supplemental interrogatory dated January 25, 2019. The Barberton store is the largest among all Giant Eagle pharmacies in Summit and Cuyahoga counties, with the greatest number of total prescriptions and controlled substance prescriptions dispensed during the period from November 2009 through May 2018. The Barberton pharmacy is across the street from the Akron Children's Hospital and within one mile of the Summa Health System Barberton Campus.

166. I have reviewed the transaction history for controlled substance orders from HBC to this store and I find that the ordering practices at the Barberton store reflect pharmacy best practices. Title 21 of the Code of Federal Regulations Section 1301.74(b) provides that distributors of controlled substances identify "…[suspicious] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[90] The pattern of orders shipped from HBC to Barberton reflects some variability during the first few months of

[89] Plaintiffs Responses to Supplemental Interrogatory Issued in Discovery Ruling 12 to Plaintiffs, January 11, 2019; Plaintiffs Responses to Amended and Clarified Discovery Ruling 12 Supplemental Interrogatory Issued to Plaintiffs, January 25, 2019.

[90] US Drug Enforcement Administration Title 21 Code of Federal Regulations. Diversion Control Division, available at: https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/130174 htm (last accessed May 10, 2019).

EXHIBIT G: INDEXED COMPARISON OF HBC HCP DISTRIBUTION IN CUYAHOGA & SUMMIT COUNTIES AND DEA QUOTAS, IN MME



Notes:
[1] HBC distributed HCP to Giant Eagle pharmacies from November 2009 to September 2014, and GERx began distributing HCP to Giant Eagle pharmacies in March 2016.
[2] Data is reported in MME, and is indexed to 2010 values.

Sources:
[A] "HBC_MDL00189212 (A1354473).xlsx" and "HBC_MDL00189213 (A1354474).xlsx."
[B] "Aggregate Production Quota History For Selected Substances," *DEA*, Harper-Avilla Exhibit 8.
[C] "full_ndc_dictionary.csv," available in the reliance materials to the Expert Report of Craig J. McCann, Ph.D., CFA, dated March 25, 2019 at the location "...\MDL Code Submission 4.23.2019\ARCOS R code\Process ARCOS and Defendant data\dictionaries"
[D] Estimated oral morphine milligram equivalent (MME) conversion factors, available at https://www.cdc.gov/drugoverdose/resources/data html (last accessed May 10, 2019).

EXHIBIT H: TOTAL PRESCRIPTIONS AND CONTROL PRESCRIPTIONS FILLED BY GIANT EAGLE PHARMACIES IN CUYAHOGA & SUMMIT COUNTIES

November 2009 - May 2018

Pharmacy	Total Prescriptions	Control Prescriptions	Control Prescriptions / Total Prescriptions
0204-North Royalton	[redacted]	[redacted]	8.8%
0208-Lyndhurst	[redacted]	[redacted]	9.8%
0209-Bedford	[redacted]	[redacted]	8.4%
0217-Middleburg Heights	[redacted]	[redacted]	8.9%
0218-City View	[redacted]	[redacted]	9.1%
0224-Twinsburg	[redacted]	[redacted]	9.3%
0228-Solon	[redacted]	[redacted]	8.8%
0230-W. 117th Street	[redacted]	[redacted]	9.5%
0440-South Euclid	[redacted]	[redacted]	6.3%
0465-Brookpark	[redacted]	[redacted]	10.0%
1216-Westlake	[redacted]	[redacted]	10.2%
1263-Cleveland	[redacted]	[redacted]	11.4%
1297-Rocky River	[redacted]	[redacted]	10.0%
1298-Lorain Ave.	[redacted]	[redacted]	9.9%
1620-Green	[redacted]	[redacted]	12.3%
2108-Berea	[redacted]	[redacted]	10.1%
4009-Snow Rd.	[redacted]	[redacted]	8.8%
4025-Fairlawn	[redacted]	[redacted]	7.9%
4029-Springfield	[redacted]	[redacted]	11.8%
4030-Tallmadge	[redacted]	[redacted]	11.5%
4031-Barberton	[redacted]	[redacted]	13.9%
4032-Stow	[redacted]	[redacted]	10.1%
4036-Portage Crossing	[redacted]	[redacted]	10.0%
4086-Strongsville	[redacted]	[redacted]	9.8%
4087-Buckeye Rd	[redacted]	[redacted]	5.9%
4088-RT 82 and I-77	[redacted]	[redacted]	8.9%
4096-Stow	[redacted]	[redacted]	8.8%
4124-Waterloo Rd.	[redacted]	[redacted]	10.2%
5810-Fairview Park	[redacted]	[redacted]	9.0%
5817-Parma	[redacted]	[redacted]	10.1%
5830-Chagrin Blvd.	[redacted]	[redacted]	6.9%
5831-Detroit Ave/Lakewood	[redacted]	[redacted]	9.9%
5836-Mayfield Heights	[redacted]	[redacted]	9.4%
5861-Fairlawn	[redacted]	[redacted]	10.3%
5878-Howe Ave.	[redacted]	[redacted]	10.9%
6299-Macedonia	[redacted]	[redacted]	9.4%
6359-North Olmsted	[redacted]	[redacted]	8.8%
6376-Biddulph Rd.	[redacted]	[redacted]	10.1%
6388-Broadview Heights	[redacted]	[redacted]	8.8%
6414-Maple Heights	[redacted]	[redacted]	5.4%
Total	[redacted]	[redacted]	**9.8%**

Notes:

[1] Duplicate data for pharmacies 4032 and 5861 have been removed.

[2] Pharmacy numbers 0201 and 0228 refer to the same pharmacy. Data are combined as pharmacy number 0228.

Source: "Weekly Rx Volume by store (A1366710) xlsx"